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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,414	11/09/2006	Todd Campbell	PA1211	4776

28390 7590 11/26/2010

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
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EXAMINER	
MEDWAY, SCOTT J	
ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
11/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No.	Applicant(s)	
	10/527,414	CAMPBELL, TODD	
	Examiner	Art Unit	
	SCOTT MEDWAY	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,7,10,12-16,18-20,22,23 and 25-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,10,12-16,18-20,22,23 and 25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/01/2010 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 26, 27, 29 and 30 are rejected under 35 U.S.C. 102(a) as being anticipated by Edgren et al (U.S. Pat. 6,245,357 B1, hereinafter "Edgren").

Regarding claims 26, 27, 29 and 30, Edgren discloses a medical implant comprising an implantable medical device having a surface and a gradient layering of two or more differing molecular weight polymers coated on at least a portion of the surface (see Fig. 3 and col.8 , lines 48-67). The gradient layering includes one or more releasable pharmaceutical compounds (14) and wherein the molecular weight polymers are selected so as to controllably affect the releasability of the compound. The device is

formed and then placed in contact with the patients body. The gradient layering comprises a highest molecular weight polymer (seen as the bottom layer in Fig. 3) closest to a surface (such as the bottom surface of the device) and the lowest weight molecular polymer layer (seen as the top layer in Fig. 3) farthest from the surface.

Claim Rejections - 35 USC § 103

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1-3, 6-8, 12-16, 18-20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kamath et al (WO 2000/32255, hereinafter "Kamath") in view of Siepmann et al (see *Understanding and Predicting Drug Delivery*, hereinafter "Siepmann"), further in view of Shwarz (U.S. Pat. 6,368,658, hereinafter "Shwarz").

Regarding claims 1-3, 6-8, 12-16, 18-20 and 23, Kamath discloses a medical implant and an associated method for its production, comprising a surface and a coating, having at least two polymer layers incorporating at least two releasable pharmaceutical compounds (pg. 11, lines 17-23), wherein the medical device is, e.g., an expandable vascular stent (pg. 8, lines 12-21) (capable of being self-expanded), and comprises polymer layers made from, e.g. silicones (pg. 15, line 21) or collagen, a known bioresorbable compound (pg. 16, line 1); wherein the pharmaceutical compound is coupled to the polymer coating by virtue of being embedded therein.

It is noted that Kamath does not disclose the compound incorporated into the polymer layers to have differing physical properties, where the physical property is molecular weight. Siepmann discloses the use of medical devices using layered coatings containing pharmaceutical compounds, where the layered coatings with different molecular weights are used to alter the effect of drug delivery (see pg. 308, "Polymer Dissolution" and Fig. 1). Since Kamath teaches that dissolution may ultimately cause drug to be delivered (pg. 24, lines 13-15), it would have been obvious for one of ordinary skill in the art at the time of the invention to try incorporating polymer layers with different molecular weights as suggested by Siepmann, since molecular weight is but one of a finite number of identified and well-known characteristics and altering that characteristic would have been obvious for one of ordinary skill in the art with the expected result of providing an improved drug delivery profile.

Regarding claims 6 and 18, it is noted that Kamath in view of Siepmann does not specifically disclose the molecular weights of the polymer types used for the medical device coating to be in the range of 1 kDa to 100,000 kDa. It would have been obvious to one of ordinary skill in the art at the time of the invention to consider implementing polymer coatings having molecular weights in this range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233*.

Regarding claims 1, 9, 10, 12, 21 and 22, it is noted that Kamath in view of Siepmann does not disclose a macrolide antibiotic, or more specifically, rapamcyin.

Shwarz discloses a drug delivery stent comprising rapamycin (col. 4, line 37), which is a known anti-restenotic compound and macrolide antibiotic. Since Kamath discloses the use of a stent for preventing restenosis, it would have been obvious to substitute a macrolide antibiotic such as rapamycin as disclosed by Shwarz for any anti-restenotic compound in Kamath, since rapamycin and the anti-restenotic compounds disclosed by Kamath are functional equivalents and substituting one for the other would be within the level of ordinary skill in the art. Additionally, it has been held that selecting a known compound such as rapamycin on the basis of its suitability for use as an anti-restenotic compound in stents is within the level of ordinary skill in the art as an obvious design choice. *In re Leshin,* 125 USPQ 416.

6. Claims 28 and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Edgren et al (U.S. Pat. 6,245,357 B1) in view of Shah (U.S. Pat. 6,020,004, hereinafter "Shah").

Regarding claims 28 and 31, it is noted that Edgren does not disclose a non-linear gradient of layers. Shah discloses that the composition of polymer layers in which drug is contained can be designed so as to effect a non-linear drug release from the polymers. Since Edgren discloses the use of different molecular weight polymer layers to modify the rate of drug release, it would have been obvious for one of ordinary skill in the art at the time of the invention to experiment with a variety of non-linear gradients since Shah suggests doing so is within the level of ordinary skill for modifying the rate of drug release to be non-linear as may be required according to patient need.

Response to Arguments

Applicant's arguments filed 05/05/2010 have been fully considered but they are not persuasive. Responding to Applicant's argument that the reference of Siepmann is only applied to tablet designs, Examiner disagrees. Siepmann specifically discloses that a large spectrum of mathematical models describing drug release has been developed for use in a wide variety of media (as acknowledged by Applicant), not merely tablets. Furthermore, it is noted that the claimed invention and the invention of Siepmann both refer to a "device", and there appears to be no structure in the claims that would differentiate the "device" of the claimed invention from the "device" of Siepmann.

Additionally, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Siepmann teaches the use of different weight polymer layers in order to control releasability of a drug, which suggests that one of ordinary skill in the art at the time of the invention could adapt different weight polymers in the device of Kamath according to the teaching of Siepmann with an expectation of success in altering the releasability of a drug.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SCOTT MEDWAY whose telephone number is (571) 270-3656. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott J. Medway/
Examiner, AU 3763
11/08/2010

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763